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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/644,687
Filing Date: August 19, 2003
Appellant(s): AVIV ET AL.

WINSTON & STRAWN, LLP
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/23/06 appealing from the Office action mailed 12/5/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,284,867

4,876,276

(9) Grounds of R jection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-16, 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloog et al., US 5,284,867 [US '867].

Kloog et al., disclose the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The formulation is emulphor or emulsions and may contain antioxidants, preferably the antioxidant is α-tocopherol. See example 3, column 12 and column 13, lines 1-5. Kloog et al., also disclose various % combinations of the emulsions in column 13, lines 5 to 23.

The HU-211 compound obtained by the process of Mechoulam et al., and used by Kloog et al., (column 2, lines 23-41 of US '867) is obtained "in pure enantiomeric form." See US 4,876,276, column 2, lines 57-62. Therefore, the phraseology "essentially free of the (3R,4R) enantiomer" is deemed (3S,4S) enantiomer is in enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer absent a showing to the contrary.

Response to Argument

In contending above rejection applicant states as follows;

> The Examiner notes that the difference between the claimed invention and Kloog is that the claims recite a compound having (3S, 4S) enantiomeric excess of at least 99.90% ove the (3R, 4R) enantiomer, while Kloog teaches that the compound is essentially free of the (3R, 4R) enantiomer.[2] The Examiner further states that the difference between 99.4% enantiomeric excess in the Kloog sample and 99.9% enantiomeric excess in the presently claimed compound is within experimental error and/or design.[3] Appellants traverse these statements and assumptions.

This is not persuasive because the statement does not relate to anticipatory rejection but rather under alternative rejection of obviousness. Applicant further argues that the Examiner admitted that Kloog et al., disclose a value different from the instant invention and therefore, the anticipatory rejection is not proper. This is not persuasive because the record shows the Examiner has never admitted such thing under anticipatory rejection.

Applicant further asserts as follows:

> A sample was prepared according to a slightly modified version of Mechoulam's original synthetic procedure ("Mechoulam sample").[9] Indeed, the Mechoulam sample obtained by the modified procedure either corresponds to the Kloog sample or is even superior to the Kloog sample, such that comparison of a true Kloog sample with the claimed compound ("Ultrapure sample") would have been less favorable to the Kloog sample.[10] Appellants therefore submit that the Mechoulam sample is representative of the closest prior art and is an equivalent or even closer comparison than the Kloog sample.

While Mechoulam's process of making the compound is inherent in the prior art of Kloog et al., the process of Mechoulam, modified to the preference of applicant, is not. Applicant contends the result on page 19 of the brief shows that Kloog's HU-211 and the instantly claimed HU-211 are significantly different. While the two samples used in the experiment may be different none of them is the same or equivalent of the sample used by Kloog et al.

The HU-211 compound obtained by the process of Mechoulam et al., and used by Kloog et al., (column 2, lines 23-41 of US '867) is obtained "in pure enantiomeric form." See US 4,876,276, column 2, lines 57-62. The term "essentially" means inherently. Therefore, "essentially free of the (3R,4R) enantiomer" means the compound of Kloog et al., is inherently free of the (3R,4R) enantiomer. In addition, applicant fails to provide any conclusive evidence that the HU-211 disclosed by Kloog et al., is not in enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kloog et al., US 5,284,867.

Applicant claims the (3S,4S) enantiomer of compound I having enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, the composition and method of use for treating various neurological disorders. The composition comprise co solvents such as polyoxyl 35 castor oil from 30-80 % W/W, ethanol from 20-70 % W/W and 0.001-0.1 % w/w of edetic acid. Applicant also claims composition having 0.1-5 % W/W of α-tocopherol.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kloog et al., teach the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The composition comprise co solvents such as ethanol, glycerol, PEG and PPG. Kloog et al., also

teach composition having 0.02 % W/W of α-tocopherol. See columns 12, lines 35 to column13, line 14.

Ascertainment of the difference between the prior art and the claims (MPEP ∋2141.02)

The difference between the instant invention and that of Kloog et al., is that applicant claims the instant compound having (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, while Kloog et al., teach the compound as essentially free of the (3R,4R) enantiomer. Also, applicant is claiming co solvents such as polyoxyl 35 castor oil from 30-80 % W/W, ethanol from 20-70 % W/W and 0.001-0.1 % W/W of edetic acid, while Kloog et al., do not teach polyoxyl 35 castor oil, edetic acid or % W/W of ethanol.

Finding of prima facie obviousness---rational and motivation (MPEP ∋2142.2413)

However, there is no evidence that the compound of Kloog et al., does not have (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer. Even if the instantly claimed compound is substantially purer than the compound of Kloog et al., there must be new and novel properties, functions or utilities arising from the higher level of purity, otherwise the instant invention is unpatentable over the prior art of Kloog et al. Also, the addition of an inert carrier, such as co-solvents, to a non-patentable compound is not patentable. *In re Best*, 562 F.2d 1252; 195 USPQ 430 (CCPA, 1977). Claiming 20-70 % ethanol and 0.1-5 % α-tocopherol are obvious modifications available to the special preference of an artisan. They are mere optimization of variables, which are not patentable absent unexpected result due to each variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller,* 22 F.2d 454,105 USPG 233 (CCPA, 1955).

Therefore, the instant invention is prima facie obvious from the teaching of Kloog et al. One of ordinary skill in the art would have known to claim compound of formula I as (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer at the time this invention

was made. The motivation is from the teaching of Kloog et al., that the compound is essentially (inherently) free of the (3R,4R) enantiomer.

Response to Argument

In quoting *In re Royka,* 180 USPQ 580 (CCPA 1974), applicant states "[t]o establish an obviousness rejection, there must be a showing that the prior art teaches or suggests each and every element of the claimed invention." Not only is the statement wrong, it is nowhere to be found in *Royka.* "The question under 35 USC 103 is not merely what the reference expressly teach[es] but what they would have suggested to one of ordinary skill in the art at the time the invention was made, *Merck & Co. Inc. v. Biocraft Labs. Inc.,* 10 USPQ2d 1843 (CAFC 1989), *quoting, In re Lamberti,* 192 USPQ 278 (CCPA 1976). The focus of an obviousness question is whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *Merck & Co. Inc. v. Biocraft Labs. Inc.* With the expectation of success, one of ordinary skill in the art would have been motivated to make compound HU-211 having enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer at the time this invention was made, given the teaching of Kloog et al., that their compound is essentially (inherently) free of the (3R,4R) enantiomer.

Applicant further asserts "that the difference between the 99.4 and 99.9 % is not within experimental error" and that "Kloog cannot obtain a higher purity than [99.4%], [therefore], his compound cannot inherently achieve the properties of the presently claimed compound." This is not persuasive because applicant fails to provide conclusive evidence to support this and similar assertions.

"Where unexpected superiority over a reference patent is relied on as the basis for allowance, evidence as to comparative test between the application and reference is a minimum

requirement, *In re Swentzel,* 104 USPQ 343, 346 (CCPA, 1955); *Blanchard Jr. v. Ooms,* 68 USPQ 314 (CADC, 1946). "In most cases the closest art will be the art relied on by the examiner, this is not always [true]. It is [possible] that two or more . . . prior arts could be equally close to the invention, and yet only one of them [is] applied against the claims by the examiner, *In re Holladay,* 199 USPQ 516 (CCPA, 1978). However, if "applicant [fails to] produce evidence that [the two prior arts] taught the same invention; it is apparent that the examiner had to find the showing insufficient". *In re Johnson,* 223 USPQ 1260, 1263 (CAFC, 1984). In the instant case, applicant modified the process of Mechoulam et al., US 4,876,276, to his preference, and asserts that the modified process is equivalent to the original process of Mechoulam et al., without any conclusive evidence/data in support thereof. Therefore, the Examiner finds the modified process insufficient. Also, the modified process is not deemed a prior art. In conclusion, applicant fails to provide a showing that the instant compound is superior to the compound of Mechoulam et al., as used by Klooq et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Conferees:

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